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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/859,651 | 05/17/2001 | Vitaliy A. Kordyum | PHAGE.001DV1 | 3897 |

20995 7590 10/21/2002

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[REDACTED] EXAMINER

LEFFERS JR, GERALD G

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1636

DATE MAILED: 10/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|-----------------------------|----------------------------------|------------------|
| Offic Action Summary | Application No. | Applicant(s) |
| | 09/859,651 | KORDYUM, ET AL. |
| | Examiner Gerald G Leffers Jr. | Art Unit 1636 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 25 July 2002.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 41-64 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.

4) Interview Summary (PTO-413) Paper No(s). _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

The following is a supplemental action mailed in response to applicants' petition, filed 7/25/02 as Paper No. 6, in which applicants provide evidence that the action mailed 11/21/01 was never received. Applicants' petition was granted in Paper No. 7, mailed 10/8/02. The supplemental action is identical to that sent 11/21/01.

Supplemental Action

Receipt is acknowledged of applicants' preliminary amendment, filed 7-24-01 as Paper No. 3, in which claims 1-40 were cancelled and new claims 41-64 added. Claims 41-64 are pending in this application.

Receipt is also acknowledged of an information disclosure statement, filed 6/18/01 as Paper No. 2. The signed and initialed PTO-1449 has been mailed with this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 41-64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 41 and 49 are vague and indefinite in that the metes and bounds of the phrase "...until a desired level of production..." are unclear. The term "desired level" does not appear to have been explicitly defined in the specification and is highly subjective, making it unclear as

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to what level of protein would satisfy the claim limitation. It would be remedial to amend the claim language to clearly indicate what level of protein production would satisfy the criteria for a “desired” level of protein.

Claim 48 is vague and indefinite in that the metes and bounds of the phrase “...wherein lysis of the *E. coli* host cell is delayed at higher multiplicities of infection relative to lower multiplicities of infection...” are unclear. It is unclear whether the phrase refers to a characteristic of the phage/host cell combination used in the method or actually refers to some additional method step. It would be remedial to amend the claim language to clearly indicate whether the phrase refers to a characteristic of the phage/host cell combination used in the method or actually refers to some additional method step.

Claims 53 and 58 are vague and indefinite in that the metes and bounds of the phrase “...providing conditions to delay lysis; and cultivating the *E. coli* host cell under a culture condition that induces lytic growth of said cell without lysis until a desired level of production...” are unclear. First, the term “desired level” does not appear to have been explicitly defined in the specification and is highly subjective, making it unclear as to what level of protein would satisfy the claim limitation. It would be remedial to amend the claim language to clearly indicate what level of protein production would satisfy the criteria for a “desired” level of protein. Secondly, it appears that the step of “providing conditions to delay lysis” and the step of “cultivating” the host cell such that lysis is delayed until a “desired” level of protein is produced are redundant. This makes it unclear what is actually intended by the phrase “...providing conditions to delay lysis...”. It would be remedial to delete this phrase as it does not appear to add anything to the claim.

Claim 63 is vague and indefinite in that it is not clear as the claim is currently written whether the step of growing a first lysogenic strain E. coli to produce a phage lysate and the step of subsequently lytically infecting a second strain of E. coli cells are practiced in the same culture or if the steps can be practiced in different cultures. For example, would infection of a strain of E. coli having a plasmid encoding a desired protein with a phage lysate prepared from a separate culture of lysogenic cells read on the claimed method? It would be remedial to amend the claim language to clearly indicate whether the cited steps are necessarily performed in the same culture of cells (e.g. a mixture of two different E. coli cell types)?

Claim 63 is also vague and indefinite in that there is no clear and positive prior antecedent basis for the term "protein" in line 9 of the claim.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliot can be reached on (703) 308-4003. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-7939 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G. Leffers Jr.
Gerald G Leffers Jr.
Examiner
Art Unit 1636

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October 11, 2002